

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jonathan S. Stamler, Eric J. Toone and Richard S. Stack

Continuation Application of

Application No.: 10/164,366

Filed: June 5, 2002

For: NOVEL POLYMERS FOR DELIVERING NITRIC OXIDE IN VIVO

Date: <u>9.23.03</u>
EXPRESS MAIL LABEL NO. <u>EV 052 030 3824 S</u>

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ A copy of the cited reference, AF2, is enclosed.
- ☒ Copies of cited references were previously entered in prior applications, U.S. Application Nos. 10/164,366, 09/752,223, now U.S. Patent No. 6,403,759 B2 and 09/103,225, now U.S. Patent No. 6,232,434, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contain copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

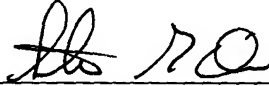
Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By



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Dated: September 23 2003

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 1818.1015-021		APPLICATION NO.				
INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 17, 2003 (Use several sheets if necessary)		APPLICANTS Jonathan S. Stamler et al.						
		FILING DATE September 23, 2003		CONFIRMATION NO.	GROUP			
U.S. PATENT DOCUMENTS								
EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE		NAME			
	AA	5,116,861	26 MAY 92		Goto et al.			
	AB	5,380,758	10 JAN 95		Stamler et al.			
	AC	5,405,919	11 APR 95		Keefer et al.			
	AD	5,482,925	09 JAN 96		Hutsell			
	AE	5,525,357	11 JUN 96		Keefer et al.			
	AF	5,519,020	21 MAY 96		Smith et al.			
	AG	5,385,940	31 JAN 95		Moskowitz			
	AH	5,504,117	02 APR 96		Gorfine			
	AI	5,427,797	27 JUN 95		Frostell et al.			
	AJ	5,385,937	31 JAN 95		Stamler et al.			
	AK	5,114,506	19 MAY 92		Consaga et al.			
	AA2	4,138,535	06 FEB 79		Schweiger			
	AB2	6,087,479	11 JUL 00		Stamler et al.			
	AC2	5,770,645	23 JUN 98		Stamler et al.			
	AD2	6,232,434	15 MAY 01		Stamler et al.			
	AE2	6,403,759 B2	11 JUN 02		Stamler et al.			
	AF2	US 2003-0078365 A1	24 APR 03		Stamler et al.			
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO	
	AL	2 244 491	04 DEC 91	UNITED KINGDOM				
	AM	WO 96/15781	30 MAY 96	PCT				
	AN	WO 95/24908	21 SEP 95	PCT				
	AO	WO 96/17604	13 JUN 96	PCT				
	AP	WO 96/16645	06 JUN 96	PCT				
	AQ	WO 96/15797	30 MAY 96	PCT				
	AL2	WO 93/20806	23 OCT 93	PCT				
	AM2	WO 94/16740	04 AUG 94	PCT				
EXAMINER				DATE CONSIDERED				

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FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS
	AN2	WO 94/22306	13 OCT 94	PCT	
	AO2	WO 95/13802	26 MAY 95	PCT	
	AP2	WO 95/13800	26 MAY 95	PCT	
	AQ2	WO 95/02408	26 JAN 95	PCT	
	AL3	WO 95/09636	13 APR 95	PCT	
	AM3	WO 95/09612	13 APR 95	PCT	
	AN3	WO 95/12394	01 MAY 95	PCT	
	AO3	WO 95/10267	20 APR 95	PCT	
	AP3	WO 95/07691	23 MAR 95	PCT	
	AQ3	WO 96/02268	01 FEB 96	PCT	
	AL4	WO 96/28145	19 SEP 96	PCT	
	AM4	WO 96/35416	14 NOV 96	PCT	
	AN4	DE 4420523	13 JUN 94	GERMANY	
	AO4	WO 96/02241	01 FEB 96	PCT	
	AP4	WO 98/05689	12 FEB 98	PCT	
	AQ4	WO 96/38136	05 DEC 96	PCT	
	AL5	WO 95/10267	20 APR 95	PCT	
	AM5	WO 95/12394	11 MAY 95	PCT	
	AN5	WO 93/12068	24 JUN 93	PCT	
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	AR	Stamler, J. S. et al. "S-Nitrosylation of Proteins with Nitric Oxide: Synthesis and Characterization of Biologically Active Compounds," <i>Proc. Natl. Acad. Sci USA</i> , 89:444-448, (1992).			
	AS	Bauer, J. A. and Ho-Leung Fung, "Chemical Stabilization of a Vasoactive S-Nitrosothiol with Cyclodextrins without Loss of Pharmacologic Activity," <i>Pharmaceutical Research</i> , 8(10):1329-1333, (1991).			
	AT	Langford, E. J. et al., "Inhibition of Platelet Activity by S-Nitrosoglutathione During Coronary Angioplasty," <i>The Lancet</i> , 344:1458-1460, (1994).			
	AU	Roy, B. et al., "New Thionitrites: Synthesis, Stability, and Nitric Oxide Generation," <i>J. Org. Chem.</i> , 59:7019-7026, (1994).			
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	AV	Gorren, A.C.F. et al., Decomposition of S-Nitrosoglutathione in the Presence of Copper Ions and Glutathione," Arch. Biochem. Biophys., 330 (2):219-228, (1996).		
	AW	Vanin, A.F. et al., "Iron Catalyzes both Decomposition and Synthesis of S-Nitrosothiols: Optical and Electron Paramagnetic Resonance Studies," NITRIC OXIDE: Biology and Chemistry, 1(3):191-203, (1997).		
	AX	Barrett, J. et al., "Photochemistry of the S-Nitroso Derivatives of Hexane-1-thiol and Hexane-1,6-dithiol," Nature, 211:848, (1966).		
	AY	Bauer, J.A. and Fung, H.L., "Chemical Stabilization of a Vasoactive S-Nitrosothiol with Cyclodextrins Without Loss of Pharmacologic Activity," Pharmaceutical Research, 8 (10):1329-1333, (1991).		
	AZ	Goldstein, S. and Czapski, G., "Mechanism of the Nitrosation of Thiols and Amines by Oxygenated *NO Solutions: The Nature of the Nitrosating Intermediates," J. Am. Chem. Soc., 118:3419-3425, (1996).		
	AR2	Askew, S.C. et al., "Catalysis by Cu ²⁺ of Nitric Oxide Release From S-Nitrosothiols (RSNO)," J. Chem. Soc. Perkin Trans., 2:741-745, (1995).		
	AS2	Batsanov, A.S., et al., "Stereocontrol in Cyclisation of Dioxolanyl Radicals," J. Chem. Soc. Perkin Trans., 1:1281-1294, (1995).		
	AT2	Feelisch M. and Stamler, J.S., "Donors of Nitrogen Oxides," Methods in Nitric Oxide Research (M. Feelisch and J.S. Stamler, eds.), pp.71-115, John Wiley & Sons, (1996).		
	AU2	Arnelle, D.R. and Stamler, J.S., "NO ⁺ , NO [•] and NO ⁻ Donation by S-Nitrosothiols: Implications for Regulation of Physiological Functions by S-Nitrosylation and Acceleration of Disulfide Formation," Archives of Biochemistry and Biophysics, 318(2):279-285, (1995).		
	AV2	Feelisch M. and Stamler, J.S., "Preparation and Detection of S-Nitrosothiols," Methods in Nitric Oxide Research (M. Feelisch and J.S. Stamler, eds.), pp. 521-539, John Wiley & Sons, (1996).		
	AW2	Zapol et al., "Kit and Inhalation Device for use with a Nitric Oxide Source," Chem Abstracts., 122: 248424.		
	AX2	Kallman et al., "Toxicity of Chemically Generated Nitric Oxide Towards Pancreatic Islet Cells can be Prevented by Nicotinamide," Life Sciences., 51:671-678, (1992).		
	AY2	Field et al., "An Unusually Stable Thionitrite from N-Acetyl-D,L-penicillamine; X-ray Crystal and Molecular Structure of 2-(Acetyl-amino)-2-carboxy-1,1-dimethyl Thionitrite," J.C.S. Chem. Comm., 249-250, (1978).		
	AZ2	Wink, D.A. et al., "Use of Nitric Oxide-Releasing Compounds as Protective Agents in Ischemia Reperfusion Injury," Chemical Abstract 123:74904 (2000).		
EXAMINER		DATE CONSIDERED		